The Comprehensive Complication Index (CCI®): Added Value and Clinical Perspectives 3 Years "Down the Line"

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The Comprehensive Complication Index (CCI®)

Added Value and Clinical Perspectives 3 Years ''Down the Line''

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Objective: To explore the added value of the comprehensive complication index (CCI®) to standard assessment of postoperative morbidity, and to clarify potential controversies for its application.

Background: The CCI® was introduced about 3 years ago as a novel metric of postoperative morbidity, integrating in a single formula all complications by severity, ranging from 0 (uneventful course) to 100 (death). It remains unclear, how often the CCI® adds to standard reporting of complications and how to apply it in complex postoperative courses.

Methods: CCI® data were prospectively collected over a 1-year period at our institution. The proportion of patients with more than 1 complication and the severity of those complications were assessed to determine the additional value of the CCI® compared to the Clavien–Dindo classification. Complex and controversial cases were presented to 90 surgeons worldwide to achieve consensus in weighing each postoperative event. Descriptive statistics were used to evaluate agreement among surgeons and to suggest solutions for consistent use of the CCI®.

Results: Complications were identified in 24% (290/1212) of the general surgical population. Of those, 44% (127/290) developed more than 1 complication by the time of discharge, and thereby CCI® added information to the standard grading system of complications. Information gained by the CCI® increased with the complexity of surgery and observation time.

Conclusions: The CCI® adds information on postoperative morbidity in almost half of the patients developing complications, with particular value following extensive surgery and longer postoperative observation up to 3 months. Each single complication, independently of their inter-connection, should be included in the CCI® calculation to best mirror the patients' postoperative morbidity.

Keywords: CCI®, classification, comprehensive complication index, morbidity, score

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LEARNING OBJECTIVES

After participating in this activity, the reader should be better able to:

1. Explain the main differences betweenn Clavien-Dindo classification and the CCI®.
2. Describe how to use, calculate and interpret the CCI®.
3. Name the added value of complication grading by the CCI®.

Objective and reproducible assessments of postoperative morbidity are central for reliable evaluation of surgical procedures and quality control.[1–3] Quality control has become increasingly important with the introduction of diagnosis-related group-systems (DRG). DRGs embrace the total costs including postoperative care. They are strongly affected by complications that are the strongest driver of costs.[4] Currently, the most widely used grading system of complications is the Clavien–Dindo classification described in 2004,[5] which was reassessed and validated 5 years after its introduction.[6] This classification ranks complications by severity based on the treatment applied to correct each respective complication, and captures complications within 5 grades. Thereby, the grades understandably reflect the magnitude of every single complication. However, complete tabulation of multiple complications is cumbersome for readers, and in the majority of studies only the highest grade of complications is reported. Thus, the Clavien–Dindo classification may not depict the entire spectrum of postoperative morbidity and underestimate burden in many studies. In addition, comparisons of patients with more than 1 complication are difficult; for example, comparing the morbidities of a patient with 2 grade 3b complications with another one experiencing 1 grade 4a and 1 grade 1 complication is not readily possible.

To overcome these shortcomings, a novel metric, the comprehensive complication index (CCI®), was developed, integrating in one single formula all recorded complications weighted by severity.[7] Of note, for the development of the CCI®, both patients and physicians were asked to rate complication scenarios on a visual analog scale from 0 to 100. Subsequently, the CCI® was developed in analogy to the operation risk index used in economic science. This index is based on the Clavien–Dindo classification and summarizes the postoperative course with a new morbidity scale ranging from 0 (no complication) to 100 (death). In addition, the CCI® easily allows

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calculation of postoperative morbidity longitudinally, for example, at discharge, 3 or 6 months after surgery.[7]

The value of the CCI® has been explored in 3 randomized controlled trials[8] showing a greater responsiveness to detect differences between treatment effects than classical endpoints such as ''any complication'' or ''major complication'' defined according to the Clavien–Dindo classification. This implies that the use of the CCI® may significantly decrease the sample sizes in future studies.[7] The CCI® has been used in large multicentric studies,[9–17] as a benchmark endpoint for major surgery,[10] or in individual centers to assess quality and individual surgeon's performance (Han-Kwang Yang, ASA 2016, personal communication).

In view of the increased use of the CCI® in several fields of surgery, this study targeted several aims: first, to prospectively assess the additional value of the CCI® compared with a standard classification of complications; second, to evaluate in which types of surgery and for which postoperative observation time the information gain is greatest. Although simple in theory, its implementation in daily clinical practice has been shown to be equivocal in complex clinical situations. Our third aim was, therefore, to clarify the application of the CCI® in complex scenarios by presenting controversial cases to a panel of international surgeons and to propose potential solutions, where no consensus was reached.

METHODS

Assessment of Postoperative Morbidity

The study targeting proper use of the CCI® in complex cases at the Department of Surgery, University Hospital Zurich, Switzerland, was conducted over a 1-year period (March 2013 to February 2014). Complications were ranked according to the Clavien–Dindo classification,[5] and the CCI® was calculated at discharge, at 1 and 3 months after surgery. Each case with 1 or more postoperative complications was routinely discussed at our weekly morbidity and mortality (M&M) conference, and controversial discussions about the final ranking of each complication for the calculation of the CCI® were recorded. The CCI® was calculated with an online tool provided on http://cci.assessurgery.com.

Patients who developed multiple complications served as the basis to assess the additional value of the CCI® for the respective surgical specialties including lower gastrointestinal tract (LGI), upper gastrointestinal tract, hepato-pancreatico-biliary, transplantation, and general surgery. A distinction was made between minor and major surgeries, in which minor procedures are defined as procedures performed without the need of an intermediate care or an intensive care unit (ICU) such as inguinal hernia repair or colon (non-rectal) surgery. Major procedures are defined as complex procedures that require surgical specialization and the availability of ICU beds, such as esophagectomies, pancreatectomies, or transplant surgery. More detailed information to differentiate minor from major procedures is available at ([accessed 22. May 2016] http://www.gdk-cds.ch/fileadmin/docs/public/gdk/themen/hsm/organe/hsm_finalreport_final_gesamt_inkl_annexe_1–7.pdf).

Online Questionnaire Design

The questionnaire included 4 questions regarding the perceived utility and practicability of the CCI® from a user point of view. In addition, 5 complication scenarios, each illustrated by 3 examples, were presented targeting 1) different complications potentially originating from a similar cause, 2) complications induced by the treatment of another complication, 3) recurrent negative events interrupted by a period of apparent healing, 4) a single complication requiring recurrent therapy; for example, multiple relaparotomies, and 5) postoperative deterioration of a preexisting condition (Suppl Table 1, http://links.lww.com/SLA/B169).

The 5 scenarios were submitted to each attending member of the Department of Surgery at the University Hospital Zurich and sent to a panel of international surgeons (n = 147) via an online questionnaire. Most of the contacted surgeons were involved in previous publications of the Clavien–Dindo classification system or familiar with the CCI®; they were predominantly members of the European Surgical Association. If no response was received, a reminder was sent by email 4 and 8 weeks after the initial invitation. All responses within 3 months after the initial contact were included in the analysis. When no consensus was found by the evaluation of the questionnaire, a proposition for potential consensus was made based on multiple discussions at the weekly M&M conferences at the Department of Surgery, University Hospital Zurich.

Statistical Analysis and Ethical Approval

Results of the CCI® and the survey were analyzed using descriptive statistics. The additional value of the CCI® was further assessed as a function of operation type (major vs. minor; surgical specialty) and time over a period of 3 months after surgery. In case of non-Gaussian distribution of our data, the Friedman Test was used to test for statistical significance. P values <0.05 were regarded statistically significant. We performed all analyses using GraphPad Prism 6.07, GraphPad Software Inc, La Jolla, CA. This study was covered by the approval of the institutional review board of the Canton Zurich, Switzerland (KEK-ZH-Nr.2016-00231). Informed consent was not necessary, as the analysis was done with anonymous, routine clinical data from our hospital. Patient data were anonymized and deidentified prior to analysis.

RESULTS

Postoperative Morbidity and Multiple Complications

During the study period, 1667 patients were admitted to the Department of Surgery at the University Hospital Zurich, of whom 290 (24%) developed at least 1 complication during hospitalisation. The distribution of complications according to the Clavien–Dindo classification is shown in Figure 1. Forty-four percent (127/290) of the patients developed more than 1 complication by the time of discharge. Patients with higher grades in the Clavien–Dindo

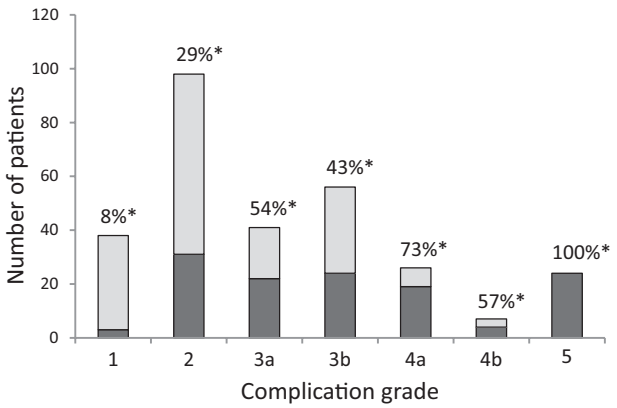

FIGURE 1. The proportion of patients presenting with 1 single complication ■ versus those with multiple complications □. *Percent refers to the proportion of patients who developed more than 1 complication.

TABLE 1. Complications (n) at Discharge Listed According to Subspecialty, Number of Complications, and Complexity of Surgery

	Overall, n (%)		Major Surgery, n (%)		Minor Surgery, n (%)	
	1 Compl	≥2 Compl	1 Compl	≥2 Compl	1 Compl	≥2 Compl
Total	163	127 (44%)	62	71 (53%)	101	56 (36%)
Tx	33	47 (59%)	27	46 (63%)	6	1 (14%)
LGI	47	32 (41%)	4	6 (60%)	43	26 (38%)
UGI	33	19 (37%)	18	7 (28%)	15	12 (44%)
HPB	24	25 (51%)	12	12 (50%)	12	13 (52%)
General	26	4 (13%)	1	–	25	4 (14%)

compl indicates complication; general, general surgery; HPB, hepatopancreaticobiliary; Tx, transplant; LGI, lower gastrointestinal tract; UGI, upper gastrointestinal tract.

classification also had a higher number of complications. For example, while only 8% of patients with a grade 1 complication had more than 1 complication, 73% of patients with a grade 4a complication developed multiple complications (Fig. 1). In order to directly compare the postoperative burden captured by the Clavien–Dindo classification and the CCI®, we calculated the median CCI® considering only the highest complication (ie, according to the Clavien–Dindo classification) versus considering all complications. Three months postoperatively, the median CCI® in patients with complications taking into account the highest complication was 26.2 [25th–75th percentile 20.9–33.7], whereas this figure increased to 33.5 [20.9–46.6] when considering all complications.

Further, we evaluated whether the ranking of complications changed if morbidity was summarized by the CCI® in comparison to the Clavien–Dindo score. After the complication categorization into quartiles, we found that 2% of patients fell into a lower quartile when using the CCI® and 24% into a higher one.

Postoperative Morbidity Based on Complexity and Type of Surgery

Fifty-three percent (71/133) of patients after major surgery developed more than 1 complication, as compared with 36% (56/157) after minor procedures (Table 1). More specifically, 63% (46/73) of patients with complications after liver, kidney, or pancreas transplantation had more than 1 complication, whereas only 14% of patients undergoing less complex surgeries, including nephrectomies or shunt procedures, developed multiple complications (Table 1). Similarly, 60% of patients with complications after extensive LGI surgery had more than 1 complication, while this was the case in only 38% (26/69) of patients undergoing less complex LGI procedures (Table 1).

Longitudinal Assessment of Postoperative Morbidity

The median CCI® (25–75th percentile) significantly increased from 25.1 (20.9 – 33.7) at discharge to 27.9 (20.9 – 39.7) at 3 months after surgery ($P < 0.01$). The overall percentage of patients with more than 1 complication increased from 44% (127/290) at discharge to 57% (170/296) at 3 months after surgery.

Evaluation of CCI® From a User Point of View

The response rate of the online questionnaire was 55% (90/165). Forty-two percent of the responding surgeons reported routine use of the CCI®, while 27% declared occasional use and 31% did not yet use the CCI®. Eighty-one percent of the participants considered the ability to assess longitudinal and long-term morbidity as one of the main advantages of the CCI®. Another 83% of the participants agreed that the minimum follow-up after surgery should be 3 months. Regarding the ideal application field of the CCI®, 72% of the surgeons would not limit the use of the CCI® to major procedures only.

Clinical Scenarios

Scenario 1: Related Complications

All 3 examples covering the first scenario illustrated complications that were related to each other, that is, originating from the same cause. Each complication was considered an individual complication by the majority of participants (agreement 76%–85%) (Fig. 2; Suppl Table 1, http://links.lww.com/SLA/B169). For example, the pancreatic fistula leading to subsequent fascial dehiscence required 2 distinct therapies for correction. Consequently, both therapies are considered additive events for the calculation of the CCI® by most of the surveyed participants.

Scenario 2: Complications Caused by a Therapy of a Prior Complication

The majority of participants considered complications that occurred as a consequence of the treatment of another event as distinct complications that need to be computed separately (agreement: 73%–87%) (Fig. 2, Suppl Table 1, http://links.lww.com/SLA/B169). For example, most participants rated a pancreatitis after

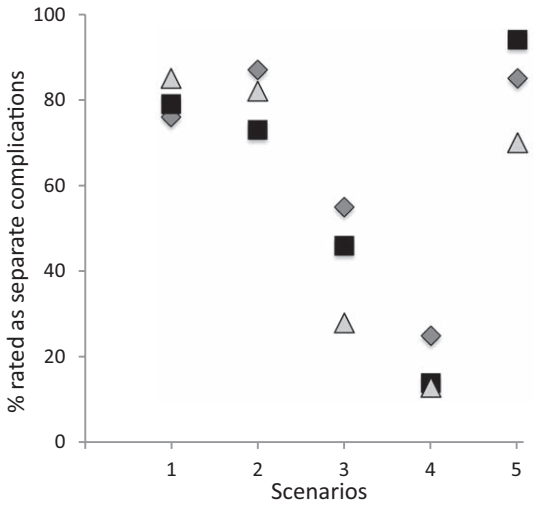

FIGURE 2. The results of the survey disclosing the percent of participants who rated each complication separately. The 3 examples (example 1 ■, example 2 ◆, and 3 Δ) for each scenario enable to assess the survey–participant agreement.

ERCP performed to treat a bile leak after hepatectomy as 2 distinct complications. Participants clearly favored the patients' perspective by acknowledging the additional burden associated with each type of complication.

Scenario 3: Two Similar Complications at an Interval

In the situation of a recurrent complication with intermittent phases of apparent healing, the responses of participants were less consistent. For example, recurrent high output stoma was considered 1 single complication by the majority of participating surgeons (72%), whereas only 46% of the participants considered recurrent ulcer bleeding occurring 2 and 4 months after surgery as 1 complication. Similarly, there was no clear consensus on how to rate a recurrent subileus with 54% of the responders considering such events as 1 complication (Fig. 2, Suppl Table 1, http://links.lww.com/SLA/B169).

Likewise, discussions on different examples of similar scenarios were controversial at the M&M conferences. Based on the discussion records from the M&M conferences, the decision whether such complications should be rated as 1 single or 2 distinct complications depends on whether a complete healing occurred between both episodes. A proposition on how to rate these scenarios will follow in the discussion (Table 2).

Scenario 4: Complications Requiring Repetitive Interventions

Consistent with the consensus of the 5-year follow-up of the Clavien–Dindo classification,[6] the majority of participants counts repetitive treatments of 1 single complication only once (Fig. 2). Whether a complication recurred at the same or different locations, for example, recurrent abscesses at different locations after open necrosectomy due to necrotizing pancreatitis, had no impact on the judgment of participants. Interpretation of the 3 examples at the M&M conference or by members of the University of Zurich provided opposite opinion with more than 60% of the participants counting those events as separate complications. Planned second looks due to 1 disease were, however, predominantly considered 1 complication (87%) (Fig. 2, Suppl Table 1, http://links.lww.com/SLA/B169). The consensus proposal will be presented in the discussion section (Table 2).

Scenario 5: Postoperative Deterioration of Preexisting Conditions

There was a consensus that postoperative deterioration of a preexisting morbidity should be regarded as a complication (Fig. 2, Suppl Table 1, http://links.lww.com/SLA/B169). For example, 85% of responding surgeons considered deterioration of renal insufficiency with subsequent need of dialysis as a complication. Further, 94% of participants rated myocardial postoperative infarction in a patient with known coronary heart disease as a complication. Interestingly, postoperative reonset of preoperatively existing intermittent atrial fibrillation requiring antiarrhythmic therapy, was considered a complication by 78% of externally asked surgeons, but only by 33% of staff members of the Department of Surgery at the University Hospital Zurich. The latter group reasoned that the intermittent atrial fibrillation was preexistent and should therefore be considered persistence of a preoperative morbidity. A proposal for how to handle those scenarios is presented below (Table 2).

TABLE 2. Proposed Consensus on How to Rate Complex Complication Scenarios for CCI® Calculation

Complication Scenario	Proposed Consensus for CCI® Calculation
Complication caused by another complication	= two complications
Complications caused by a therapy applied to treat another complication	= two complications
Two similar complications at an interval	= two complications
One Complication requiring repetitive interventions	= separate complications
Planned second look	= one single complication
Postoperative deterioration of a preexisting morbidity	= one complication

DISCUSSION

In this study, we demonstrated the added value of the CCI® to the tabulated complications listed by severity with a need to record both approaches, at least following major surgeries. Morbidity should be consistently reported at 3 months after surgery for all procedures. The other main message was to clarify how to use the CCI® in complex postoperative courses.

The widely used tabulated form of reporting postoperative complications by the Clavien–Dindo system is based on the type of therapy required to treat the complication. This system is an objective, simple, reliable, and reproducible way of reporting negative events after many types of surgery.[6] Although this classification allows the complete reporting of multiple complications in a patient, this approach is undoubtedly cumbersome to interpret. In fact, many centers using the Clavien–Dindo classification focus only on the most severe complication. Thus, a limitation of this classification is that events of lesser severity may not be considered, leading to an underestimation of the true overall postoperative morbidity.

This is where the additional use of the CCI® comes into play. The CCI® facilitates comparisons of patients with more than one complication, as all postoperative events including their respective severity are taken into account for its calculation. As an appealing facet of the formula, it offers a ''common sense'' scale ranging from 0 (uneventful course) to 100 (death).

During an observation period of 12 months, 44% (127/290) of patients with complications after abdominal surgery developed more than one postoperative complication. Thus, the CCI® offers additional information on morbidity in about half of the patients with a complicated course. The information gain depends on the extent and specialty of surgery. Moreover, there was an association between the number of complications and time after surgery as the percentage of patients with postoperative complications developing more than one complication increased from 44% at discharge to 57% three months after surgery. This study therefore highlights the need to collect data on postoperative morbidity for at least 3 months after surgery, which is in line with previously published studies.[10,18,19]

In many areas surrounded by controversies regarding definitions, grading of events, or equivocal data, a consensus approach may offer solutions leading to wider acceptance.[20–22] Such a consensus was achieved by evaluating difficult clinical situations after the initial introduction of the Clavien–Dindo classification.[6] We felt that a similar exercise is justified 3 years after the introduction of the CCI® due to its increasing use in retrospective, prospective, and benchmark studies.[10] Perhaps the CCI® will become a standard endpoint in the benchmark evaluation of a variety of surgeries. Therefore, early consistent use of the CCI® is paramount to ensure comparability of data among studies in the future. For this purpose, scenarios representing cases identified as equivocal during the M&M conference were sent to surgeons worldwide for assessment. An

overall consensus was documented for scenarios describing either complications originating from the same cause, or from the treatment of another complication, as well as events resulting from the deterioration of preexisting conditions. A summary of the final recommendations is presented in Table 2.

Of note, 2 scenarios failed to reach a consensus with the international survey, namely how to grade repetitive intervention to correct 1 single complication or recurrent complications after apparent intermittent healing (scenarios 3 and 4). From the patients' perspective, postoperative morbidity is clearly higher for events requiring multiple interventions, compared with a single one. The proposed consensus is to consider recurrent episodes as distinct complications and to count each intervention separately for CCI® calculation, with the exception of ''planned'' second look operations. The main argument for this exception is to avoid surgeons denying ''second look'' laparotomies to minimize their recorded morbidity by CCI®. Second, patients requiring multiple planned second looks are prone to be on the ICU with an overall high postoperative complication rate. This will be captured anyway by the CCI® through monitoring of other complications.

To secure standardization in the use of the CCI®, and particularly for proper grading of complications, frequently asked questions are available on http://assessurgery.com/about_cci-calculator. A mobile and tablet version is also ready to use (http://cci.assessurgery.com) for the calculation of the CCI® by entering the respective Clavien–Dindo complication grades per patient.

This study has some limitations. As the CCI® is based on the Clavien–Dindo classification, there is no improvement regarding the interuser reliability of the new scoring system. However, the reproducibility of the Clavien–Dindo classification was previously shown to be high.[5] Further, the CCI® does not include risk adjustment for preoperative morbidity. The CCI® is exclusively a marker for postoperative morbidity. Patients in high-volume centers are more likely to present with significant comorbidities and will therefore be more prone to develop a higher CCI®. It is clear that comorbidities must be included in any objective risk-adjusted comparison.

Of note, not every undesirable postoperative event should be considered a complication. There are two others types of negative outcome.[23] Any unavoidable consequence of a procedure, referred to as ''sequela'', differs from a complication by its predictability. For example, the inability to walk after a leg amputation is a sequel, not a complication. Also ''failure to cure'' - describing the failure of achieving the goal of an intervention - is not a postoperative complication, e.g. a R2 resection, while the aim of surgery was a curative resection.[23]

In conclusion, the CCI® has been shown to yield a substantial additional value to the Clavien–Dindo classification in patients with more than 1 complication. Especially after major surgery and with inclusion of the observation time after surgery, its value increases. This, however, does not justify a replacement of 1 system by the other as the Clavien–Dindo classification discloses the highest grade of complications and the type of complications. Therefore, in future studies both systems should be routinely used for recording postoperative studies following the recommendations and propositions made above on the use of the CCI®.

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